

1 **We claim:**

- 1 1. A crystalline form R of atorvastatin hemi calcium and hydrates thereof.
- 1 2. Crystalline atorvastatin hemi calcium form R or a hydrate thereof having a powder
2 XRD pattern substantially as depicted in FIG. 1.
- 1 3. Crystalline atorvastatin hemi calcium form R or a hydrate thereof having IR
2 spectrum substantially as depicted in FIG. 2.
- 1 4. The crystalline form R of atorvastatin hemi calcium of claim 1 exhibiting an XRD
2 spectrum comprising characteristic peaks at about 8.62, 10.16 and 19.32 degrees
3 two-theta.
- 1 5. The crystalline form R of atorvastatin hemi calcium of claim 1 further comprising
2 peaks at about at 3.6, 8.24, 18.12, 18.36, 20.44, 20.82, 21.22 and 23.82 degrees
3 two-theta.
- 1 6. A process for preparing crystalline form R of atorvastatin hemi calcium and
2 hydrates thereof comprising dissolving crude atorvastatin hemi calcium in a
3 solvent system comprising tetrahydrofuran and methanol and recovering Form R
4 atorvastatin hemi calcium or hydrates thereof.
- 1 7. The process according to claim 6 wherein crude atorvastatin is any of the
2 polymorphic form reported earlier.
- 1 8. The process according to claim 6 wherein crude atorvastatin hemi calcium contains
2 unreacted compounds, side products or other impurities.
- 1 9. The process according to claim 6 wherein mixture of crude atorvastatin hemi
2 calcium and solvent system is heated up to reflux.
- 1 10. The process according to claim 6 wherein Crystalline form R of atorvastatin hemi
2 calcium and hydrates thereof is precipitated by addition of an anti solvent.
- 1 11. The process according to claim 10 wherein an anti solvent is water.
- 1 12. The process according to claim 6 wherein Crystalline form R of atorvastatin hemi
2 calcium and hydrates thereof is isolated by cooling the reaction mixture to a
3 temperature of about 20 to 40°C.

- 1 13. The process according to claim 6 and 11 wherein tetrahydrofuran, methanol and
2 water are in the volume ratio 1:1:4.
- 1 14. A process for the preparation of stabilized amorphous form of atorvastatin hemi
2 calcium comprising dissolving crystalline Form R of atorvastatin hemi calcium and
3 hydrates thereof in a solvent, and adding the anti-solvent to the resulting solution.
- 1 15. The process according to claim 14 wherein solvent is selected from the group
2 consisting of ketones, esters, chlorinated hydrocarbons, cyclic ethers, alcohols,
3 nitriles, dipolar aprotic solvents and mixtures thereof.
- 1 16. The process according to claim 14 wherein anti solvent is selected from the group
2 consisting of hydrocarbons and dialkyl ethers.
- 1 17. The process according to claim 14, wherein an antioxidant is added to the
2 atorvastatin hemi calcium solution to obtain stabilized amorphous atorvastatin
3 hemi calcium.
- 1 18. The process according to claim 17, wherein an antioxidant is selected from the
2 group consisting of butylated hydroxyanisole, butylated hydroxytoluene and
3 tertiary-butylated hydroquinone.
- 1 19. A pharmaceutical composition comprising crystalline form R of atorvastatin hemi
2 calcium or hydrates thereof along with pharmaceutically acceptable excipients,
3 diluents and carriers.
- 1 20. A method for treatment or prevention of hyperlipidemia, hypercholesterolemia,
2 Alzheimer's disease atherosclerosis, xanthoma and in synergism with other drugs
3 for treatment of phytosterolemia lipase deficiency and the like, which comprises
4 administering to a patient in need thereof, a therapeutically effective amount of
5 Crystalline Form R of atorvastatin hemi calcium or hydrates thereof.
- 1 21. The use of crystalline form R of atorvastatin hemi calcium and hydrates thereof in
2 the manufacture of a medicament for the treatment or prevention of
3 hyperlipidemia, hypercholesterolemia, Alzheimer's disease, atherosclerosis,
4 xanthoma and in synergism with other drugs for treatment of phytosterolemia
5 lipase deficiency and the like.

- 1 22. A process for preparing crystalline form R of atorvastatin hemi calcium and
2 hydrates thereof comprising dissolving crude atorvastatin hemi calcium in a
3 mixture of tetrahydrofuran and methanol, and precipitating with water to obtain
4 crystalline form R of atorvastatin hemi calcium.
- 1 23. The process for the preparation of Crystalline Form R of atorvastatin hemi calcium
2 or hydrates thereof as herein described and illustrated by the examples herein.